REMARKS

Claims 57-59, 62-66 and 74 were pending prior to this Response. By the present communication, no claims have been added, claim 74 has been canceled without prejudice, and claims 57 and 59 have been amended to recite Applicant's invention with greater particularity. The amendment does not raise any issues of new matter and the amended claims do not present new issues requiring further consideration or search, being fully supported by the Specification and original claims. Accordingly, claims 57-59, 62-66 are currently pending in this application.

Objections to the Claims

Applicants respectfully traverse the objection to claims 59, 62, 63 and 66 as allegedly containing minor informalities. However, in order to reduce the issues and further prosecution, Applicants have amended claim 59 to insert the term "one," as suggested by the Examiner. Accordingly, withdrawal of the objections is respectfully requested.

Objections to the Specification

Applicants respectfully traverse the objection to the specification as allegedly not complying with the sequence rules under 37 C.F.R. §§1.821-1.825. Specifically, the Examiner alleges that the legends of Figures 3-5 and 19-25 do not provide the SEQ ID numbers of the peptides used in the experiments. In order to reduce the issues and further prosecution, Applicants have amended paragraphs 0024-0026 and 0033-0037 to insert sequence identifiers. Support for the amended paragraphs may be found, among others, in paragraph 0042 of the specification as filed. Accordingly, withdrawal of the objection is respectfully requested.

The Examiner further objects to the sequence listing of record as allegedly listing an institution as an inventor of the application. Applicants submit that the sequence listing of record does not list "The Regents of the University of California" as an inventor. The PatentIn software used to generate the sequence listing inserts the organization name in the first line of field <110>, followed by the list of inventors. Applicants have verified the output of the PatentIn 3.3

software, and compared the same to the "Hands-On Training Manual" for PatentIn, Version 3.3 (see page 9). Applicants have further contacted the Patent Office to determine if an organization name should not be included in field <110>, and were directed to Supervisory Patent Examiner Christopher Low. SPE Low confirmed that an organization name, if entered into the PatentIn software, will appear in the first line of section <110>, and offered to answer any further questions that the Examiner may have with regard to the sequence listing. Accordingly, withdrawal of the objection is respectfully requested.

Rejection Under 35 U.S.C. § 101

Applicants respectfully traverse the rejection of claims 64 and 65 under 35 U.S.C. §101 as allegedly not being supported by either a specific and substantial asserted utility or a well established utility. Specifically, the Examiner alleges that a composition that comprises a pro-inflammatory peptide and an anti-inflammatory cytokine comprises activities that cancel each other and would therefore not induce a pro-or anti-inflammatory response upon administration.

Applicants respectfully submit that the intended utility of the invention includes use of treatment regimens wherein peptides and cytokines of seemingly opposing effects are administered. Such treatment regimens may be thought of as selective manipulation of the immune response, and in particular, variable modulation, which is analogous to the effect of a "dimmer switch," wherein the response can be tailored to the disease state.

The claimed invention provides a combination of two "apparently" opposite acting active ingredients (for example, an immunomodulating peptide and a cytokine, or two peptides each eliciting increases in opposite acting cytokines with respect to inflammation/tolerance), which as one of ordinary skill in the art would understand, induces an intermediate state in the immune response (i.e., between inflammatory and regulatory), thereby tailoring the response to the specific application. Applicants submit that such administration would not "cancel each other" because the immune pathways that are used/activated and the signaling induced by the ingredients channel differently. For example, as one induces the presence of a particular set of

cytokines resulting in inflammatory signaling to tissues, the other may induce down regulation of inflammation caused by other cellular activities, such as a cellular response to elicit tolerance.

Applicant respectfully direct the Examiner's attention to the Background section of the specification, which notes in the first paragraph the short comings of the prior art for treatments directed to alleviating the symptoms of a disease not the causation. The section ends (page 2, top paragraph) noting that the present invention seeks to "specifically" modulate response. The specification further discloses (various places) that the invention seeks to both alleviate symptoms, such as by lowering inflammation by administering appropriate cytokines or inducing a tolerating state with a modulatory peptide, and prevent disease activation such as by administration of peptides that mimic those associated with the disease state and inducing tolerance, or alternatively, inducing an inflammatory immune response to elicit antibody production. Paragraph 0009, among others, sets forth the objective of the invention, which includes administration of pro-, anti-, and mixtures of both pro- and anti-inflammatory peptides. The induction of various cytokines suggests to one of skill in the art that a variety of immunological effects on the host immune system are available by using the compositions of the invention. Clearly, activation of any one kind of cytokine is resultant of activation of a specific biological pathway. Further, different peptides elicit immune responses at different levels and by means of varying pathways.

Applicants further direct the Examiner's attention to the specification at paragraph 0010 (and paragraph 0076, end), which discloses an aspect of the invention that is directed to "reducing" or "inhibiting" an inflammatory or an anti-inflammatory response. Applicants submit that "reducing" may be understood by one of skill in the art as treating a symptom, while "inhibiting" may be understood as affecting a pathway, or vice versa. Thus, the use of the two different terms suggests that two different activities or effects, which are not necessarily opposing or canceling one another, are possible. Further, as noted in paragraph 0039, the variety of contexts in which the invention can be used to modulate includes use of both pro- and anti-inflammatory routes together. Finally, paragraph 0043 discloses a variety of "effector cells" that

can play a role in the immune response, which is clearly recognizable by one of skill in the art as affecting numerous pathways, and not necessarily canceling one another.

Applicants further direct the Examiner's attention to the specification at paragraph 0077, which defines the immunizing conditions and tolerizing conditions under which the peptides of the invention may be administered. Paragraph 0078 then discusses the types of situations for which the therapy can be applied. Thus, one of skill in the art would recognize that a variety of modulation manipulations can be performed, e.g., where the patient cannot mount a proper immune response. For example, one can administer an inflammatory peptide to enhance an antibody response while administering a tolerating peptide to lessen inflammation caused by the reaction to self-peptide.

Accordingly, for the reasons provided above, Applicants submit that use of peptides exhibiting allegedly opposing activities has patentable utility as disclosed in the specification. Applicants respectfully request withdrawal of the rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph

Applicants respectfully traverse the rejection of claims 64 and 65 under 35 U.S.C. §112, first paragraph, as allegedly not being supported by either a specific and substantial asserted utility or a well established utility. The arguments submitted herein above with regard to the rejection under 35 U.S.C. §101 apply equally and are incorporated herein. Accordingly, Applicants respectfully request withdrawal of the rejection.

Applicants respectfully traverse the rejection of amended claim 58 under 35 U.S.C. §112, first paragraph, as allegedly being new matter. Applicants submit that use of the term "operatively" was merely descriptive, and was thus intended to describe (as defined in paragraph 0056, lines 5-8) that "two or more peptides…are joined together such that the functions of the linked peptides…is maintained, and such that the chimeric polypeptide…exhibits the functions of each component of the peptide." Thus, the two or more distinct peptides are in and of themselves each active, as opposed to being changed into or "operative" with respect to something else. Thus, even without the term "operatively," the peptides would by necessity have

to be operative. Accordingly, deletion of the term "operatively" does not expand the scope of the originally filed claim since each of the peptides must necessarily have the activity disclosed in the specification. Withdrawal of the rejection is requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Applicants respectfully traverse the rejection of claim 58 under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner alleges that the specification does not teach the metes and bounds of linked sequences. As discussed above, Applicants submit that the deletion of the term "operatively" does not change the scope of the claimed chimeric peptide. The two peptides are linked such that the functions of the linked peptides is maintained. Accordingly, claim 58 clearly encompasses polypeptides comprising two distinct peptide sequences, each active in their ability to induce either an inflammatory or a tolerogenic immune response. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

No fee is believed to be due in connection with filing this paper. However, the Commissioner is hereby authorized to charge any fees that may be required by this paper, or credit any overpayment to Deposit Account 07-1896 referencing the above-identified attorney docket number. A duplicate copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

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